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HOUSE BILL 1470
By Jones, S.

AN ACT to amend Tennessee Code Annotated, Title 68, to enact the "Renal Dialysis Protection Act".

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 68, Chapter 1, is amended by adding the following language as a new, appropriately designated part:

Section 68-1-1901. This act shall be known and may be cited as the "Renal Dialysis Patient Protection Act".

Section 68-1-1902. As used in this part, unless the context otherwise requires:

(1) "Department" means the Tennessee department of health;

(2) "Hospital" means an institution licensed or regulated as a hospital by the department or a facility owned or operated by the federal government; and

(3) "Renal dialysis facility" means a place, other than a hospital or the patient's home, that provides therapeutic care for persons with acute or chronic renal failure through the use of hemodialysis, peritoneal dialysis or any other therapy that clears the blood of substances normally excreted by the kidneys.

Section 68-1-1903. No hospital or renal dialysis facility in this state shall reuse blood tubing or transducer protectors.

Section 68-1-1904. No hospital or renal dialysis facility in this state shall reuse a hemodialyzer or dialyzer caps on a patient unless, prior to the initial treatment, that patient has first signed a written consent form after having been orally advised by a physician of the potential risks, benefits and uncertainties surrounding reuse and the disinfection process. The information conveyed shall consist of a full and fair presentation of representative opinions from those in the medical community who have expressed concerns about reuse practices and from those who support these practices. Any discussion of first use syndrome shall include information about advances in biocompatible-membrane technology. Treatment shall not be withheld nor shall a patient be otherwise penalized if the patient declines reuse.

Section 68-1-1905. Dialysis patients shall have the following rights:

(1) To revoke or limit, either orally or in writing, a previously executed reuse consent at any time and for any reason;

(2) To be informed before each dialysis treatment of the number of times the dialyzer and dialyzer caps have been previously used;

(3) To have documented in their patient care records all consents to reuse, refusals to consent, revocations of consent and limitations placed upon consent;

(4) To have unrestricted access to their patient dialysis care records; and

(5) To make the reuse consent decision as required under § 68-1-1904 in an environment devoid of threats, intimidation or retaliation by the facility or its staff.

Section 68-1-1906.

(a) The department shall promulgate rules and regulations applicable to all hospitals and renal dialysis facilities in this state with respect to the following:

(1) The labeling, handling, transporting, storage, routine inspection and preventive maintenance of dialysis equipment;

(2) The reprocessing and reuse of hemodialyzers, dialysate port caps and blood port caps;

(3) Water purification and quality;

(4) The flushing of residues from potentially toxic sterilants and disinfectants used during manufacturing or reprocessing;

(5) The responsibility to ensure individualized treatment, including the most appropriate choice of equipment for each patient and, for patients exhibiting hypersensitivity, the use of biocompatible membranes;

(6) The reporting of equipment failures and occurrences of pyrexia, sepsis or bacteremia;

(7) The training, minimum qualifications and supervision of dialysis staff;

(8) The training and support provided to self-dialysis and home-dialysis patients; and

(9) The nonwaivable dialysis patients' rights enumerated under § 68-1-1905.

(b) The rules and regulations promulgated under subsection (a) shall not be less stringent than the guidelines set forth in the most current edition of the Recommended Practice for Reuse of Hemodialyzers published by the Association for the Advancement of Medical Instrumentation, and the recommendations of the Centers for Disease Control referenced in those guidelines.

(c) Until the rules and regulations promulgated under subsection (a) become effective, hospitals and renal dialysis facilities shall comply with the

guidelines set forth in the Recommended Practice for Reuse of Hemodialyzers, except that, where there are recommendations of the Centers for Disease Control, hospitals and renal dialysis facilities shall comply with the Centers for Disease Control recommendations.

SECTION 2. This act shall take effect July 1, 2001, the public welfare requiring it.